



## Medical Necessity Criteria for Overactive Bladder Medications

### Drug Class – Overactive Bladder (OAB) Medications

**Background** – After evaluating the relative clinical and cost effectiveness of the OAB medications, the DoD P&T Committee recommended that the following medications be designated as non-formulary: tolterodine immediate release (Detrol), fesoterodine (toviaz), oxybutynin gel (Gelnique) and trospium immediate release (Sanctura). This recommendation has been approved by the Director, TMA.

**Effective Date:** 11 Feb 2009, 28 Oct 2008; 14 April 2010

Patients currently using a nonformulary OAB medication may wish to ask their doctor to consider a formulary alternative.

### Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.
3. Oxybutynin immediate release is a short-acting OAB medication that may require dosing from two to four times daily; other formulary OAB medications are longer-acting and require less frequent dosing. While a short-acting product may shorten the duration of adverse effects (such as dry mouth) in patients using these medications on an "as needed" basis, longer-acting medications in general cause fewer adverse effects and are preferred for chronic treatment. Patients are not required to have tried oxybutynin immediate release.

### Medical Necessity Criteria for Overactive Bladder Medications

The non-formulary cost share for tolterodine immediate release (Detrol), trospium immediate release (Sanctura), oxybutynin gel (Gelnique) or fesoterodine (Toviaz) may be reduced to the formulary cost share if the patient meets any of the following criteria:

1. Use of ALL of the following formulary OAB medications (Detrol LA, Ditropan XL, Enablex, Oxytrol, Sanctura XR, and Vesicare) is contraindicated.
2. The patient has experienced significant adverse effects from ALL of the following formulary OAB medications (Detrol LA, Ditropan XL, Enablex, Oxytrol, Sanctura XR, and Vesicare) that are not expected to occur with the non-formulary OAB medication.

*Criteria approved through the DoD P&T Committee process November, 2009*

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# TRICARE Pharmacy Program Medical Necessity Form for Overactive Bladder (OAB) Medications



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This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- **Detrol LA (tolterodine sustained-release), Ditropan XL (oxybutynin sustained-release), Enablex (darifenacin), Oxytrol (oxybutynin patch), Vesicare (solifenacin), and oxybutynin immediate-release** are the formulary OAB medications on the DoD Uniform Formulary.
- **Detrol (tolterodine immediate-release), Gelnique (oxybutynin topical gel), Sanctura (trospium), and Toviaz (fesoterodine) are non-formulary, but available to most beneficiaries at the non-formulary cost share.**
- You do **NOT** need to complete this form in order for non-active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary medications at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication instead of a formulary medication is medically necessary. If a non-formulary medication is determined to be medically necessary, non-active duty beneficiaries may obtain it at the formulary cost share.
- Active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary. There is no cost share for active duty service members at any DoD pharmacy point of service.

|                                      |  |            |
|--------------------------------------|--|------------|
| <b>MAIL ORDER<br/>and<br/>RETAIL</b> | <ul style="list-style-type: none"><li>• The provider may <b>call: 1-866-684-4488</b> or the completed form may be <b>faxed to: 1-866-684-4477</b></li><li>• The patient may attach the completed form to the prescription and <b>mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954</b> or <b>email the form only to: TPharmPA@express-scripts.com</b></li></ul>  | <b>MTF</b> |
|                                      | <ul style="list-style-type: none"><li>• Non-formulary medications are available at MTFs only if <b>both</b> of the following are met:<ul style="list-style-type: none"><li>▪ The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.</li><li>▪ The non-formulary medication is determined to be medically necessary.</li></ul></li><li>• Please contact your local MTF for more information. There are no cost shares at MTFs.</li></ul> |            |

## Step 1 Please complete patient and physician information (please print)

|                      |                       |
|----------------------|-----------------------|
| Patient Name: _____  | Physician Name: _____ |
| Address: _____       | Address: _____        |
| Sponsor ID#: _____   | Phone #: _____        |
| Date of Birth: _____ | Secure Fax #: _____   |

## Step 1. Please indicate which medication is being requested:

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### 2. Please explain why the patient cannot be treated with any of the formulary medications:

Please indicate which of the reasons below (1-3) applies to each of the formulary medications listed in the table. You **MUST** circle a reason **AND** supply a written clinical explanation specific for **EACH** formulary medication.

| Formulary Medication                          | Reason | Clinical Explanation |
|---|--------|----------------------|
| Darifenacin<br>(Enablex)                      | 1 2 3  |                      |
| Oxybutynin patch<br>(Oxytrol)                 | 1 2 3  |                      |
| Oxybutynin sustained-release<br>(Ditropan XL) | 1 2 3  |                      |
| Solifenacin<br>(Vesicare)                     | 1 2 3  |                      |
| Tolterodine sustained-release<br>(Detrol LA)  | 1 2 3  |                      |

The criteria do not include oxybutynin immediate-release as a formulary alternative due to its multiple daily dosing requirement and greater incidence of adverse effects (e.g., dry mouth) when used chronically, compared to longer-acting OAB medications. Patients are not required to have tried oxybutynin immediate-release.

### Acceptable clinical reasons for not using a formulary medication are:

1. The formulary medication is contraindicated (e.g., due to a hypersensitivity reaction).
2. The patient has experienced significant adverse effects with the formulary medication that are not expected to occur with the non-formulary OAB medication.
3. **Detrol, Sanctura, or Toviaz request only** - An adequate trial of the formulary medication resulted in therapeutic failure.

## Step 3 I certify the above is correct and accurate to the best of my knowledge. Please sign and date:

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|                               |               |
|-------------------------------|---------------|
| _____<br>Prescriber Signature | _____<br>Date |
|-------------------------------|---------------|